

Re-evaluation Decision

RVD2010-03

Diquat Dibromide

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Re-evaluation Decision

After a re-evaluation of the herbicide diquat dibromide (herein referred to as diquat), Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the <u>Pest Control Products Act</u> and Regulations, is granting continued registration of products containing diquat for sale and use in Canada.

An evaluation of available scientific information found that products containing diquat do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of diquat uses, new risk-reduction measures must be included on the labels of all products. No additional data are required at this time.

The regulatory approach for the re-evaluation of diquat was first presented in Proposed Re-evaluation Decision PRVD2008-12, *Diquat Dibromide*, a consultation document. This Re-evaluation Decision describes this stage of PMRA's regulatory process for the re-evaluation of diquat as well as summarizes the Agency's decision and the reasons for it. Comments received during the consultation process resulted in some revisions to the required label statements. Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-12. To comply with this decision, the registrant of products containing diquat will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

[&]quot;Consultation statement" as required by subsection 28(2) of the Pest Control Products Act.

^{2 &}quot;Decision statement" as required by subsection 28(5) of the Pest Control Products Act.

Diquat, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- · it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of diquat. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy).

The USEPA re-evaluated diquat and published its conclusions in a 1995 RED, the 2002 Report of the *Food Quality Protection Act* Tolerance Reassessment Progress and Risk Management Decision (TRED), and the notice of the label requirements modification published in the 2002 Federal Register.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-12, *Diquat Dibromide*.

What Is Diquat?

Diquat is a herbicide that is used as a desiccant on terrestrial food and feed crops and on industrial oilseed and fibre crops. Diquat is also registered for weed control (chemical mowing) of non-cropland and as a restricted aquatic herbicide to control water weeds and algae in still and slow-moving waters of farm dugouts, ponds and ditches, and in lakes.

Diquat can be applied to terrestrial sites by ground or aerial equipment. For aquatic application, it can be injected below the water surface from a boat travelling in lines at regular intervals across the water or sprayed or poured directly on the surface of the water while moving in a boat or from the banks of small bodies of water. Equipment used by commercial applicators to spray diquat on the water surface includes a closed system sprayer, often a hose and handgun, or a backpack sprayer.

Health Considerations

Can Approved Uses of Diquat Affect Human Health?

Diquat is unlikely to affect your health when used according to the revised label directions.

People could be exposed to diquat through consumption of food and water, through residential exposure, by working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that diquat was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The Food and Drugs Act prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for Food and Drugs Act purposes through the evaluation of scientific data under the Pest Control Products Act. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Diquat is currently registered in Canada for use on beans (white and red kidney, soy and adzuki), canola, chickpeas, flax (including low linolenic acid varieties), legume forage seed crops (alfalfa, birdsfoot trefoil, red clover and white clover), lentils, mustard (condiment type only), oats (for corn spurry control), peas (field or dry), potato (vine killing), sweet white lupins, sunflowers, stale seedbed (beans, beets, carrots, cole crops, corn, onions, peas, cucumbers, potatoes, soybeans and turnips), vegetables (for inter-row directed weeding only) and for perennial grass suppression under apple trees. Diquat may also be used in other countries on crops that are imported into Canada. MRLs for diquat are established for the following commodities: lentils at 0.2 ppm; flax and solin at 0.5 ppm; and eggs, meat and meat by-products, milk, poultry and poultry meat by-products at 0.05 ppm. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)].

If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Diquat Is Introduced Into the Environment?

Diquat is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target organisms (for example, birds, mammals, insects, aquatic organisms, and terrestrial plants) could be exposed to diquat in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of diquat was acceptable provided risk-reduction measures to further protect the environment were implemented. This conclusion applies to the Canadian situation, and equivalent risk-reduction measures (re-application interval for aquatic uses) as well as advisory environmental label statements are required. Furthermore, the PMRA has proposed aquatic and terrestrial buffer zones for terrestrial (for example, agricultural crops, rights-of-way, chemical mowing) uses of diquat to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of diquat, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixers/loaders/applicators
- A closed system requirement for mixers/loaders supporting aerial application
- A restricted-entry interval to protect workers re-entering treated sites

Environment

- Buffer zones to protect non-target sensitive aquatic and terrestrial habitats
- A minimum re-application interval of two weeks for direct aquatic applications to further protect aquatic organisms
- Additional environmental hazard statements

Appendix II lists all required label amendments, including instructions related to basic hygiene practices.

Other Information

Any person may file a notice of objection³ regarding this decision on diquat within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

As per subsection 35(1) of the Pest Control Products Act.



Appendix I Comments and Responses

1.0 General Comment

The registrant indicated that changes to the label requirement of the 1995 RED regarding personal protective equipment were implemented by the USEPA following the review of new data submitted by the Registrant.

Response

The PMRA acknowledges the publication of the 2002 USEPA Assessing Syngenta's Request to Modify Diquat Bromide Label Requirements document and took it into consideration while addressing the Registrant comments.

2.0 Comment on the Maximum Residue Limits

Following the completion of the American Diquat Dibromide Tolerance Re-assessment Decision published in April 2002, tolerances established in the Tolerance Reassessment Progress and Risk Management Decision differ from those proposed in Canada. Harmonization of the Canadian MRLs with the established American tolerances has been proposed.

Response

An application, adequately supported by relevant scientific data, may be submitted to the PMRA in order to support changes to the established MRLs for diquat.

3.0 Comment on the Mixer/Loader/Applicator Exposure and Risk Assessment

3.1 Toxicity endpoint for Dermal Exposure

The dermal toxicity endpoint for diquat was re-assessed by the USEPA. The no observed adverse effect level (NOAEL) changed from 20 mg/kg bw/day based on the 21-day dermal rabbit study to an oral NOAEL of 1 mg/kg bw/day based on the developmental toxicity study in the rabbit.

Response

The dermal toxicity endpoint used in the re-evaluation of diquat was based on the repeated dermal toxicity study in the rat (NOAEL of 20 mg/kg bw/day). In 2002, the USEPA determined that the study was not appropriate for the risk assessment because the skin of the rats used in this study was compromised. Consequently, the USEPA extrapolated a dermal toxicity endpoint from a short-term oral study in the rabbit (NOAEL of 1 mg/kg bw/day).

On this basis, the newly selected dermal endpoint (1 mg/kg bw/day) is accepted by the PMRA and was used in the revised risk assessment for commercial workers. There were no significant changes to the re-evaluation decision as a result of this revision.

3.2 Dermal Absorption Factor

A new dermal absorption factor of 0.3% based on the Feldman and Maibach (1974) study was accepted by the USEPA for the assessment of the potential dermal daily exposure.

Response

The PMRA concluded that due to several limitations of the Feldman-Maibach study, a dermal absorption factor of 0.3% is not acceptable. These limitations reduce the level of confidence in this one study. Given the limitations the results of this study have been used previously only in a "weight of evidence" approach along with the results of other dermal absorption studies to estimate a dermal absorption value.

Based on a dermal absorption study in rats (male Sprague-Dawley) reported in the 1995 RED for diquat, the PMRA concluded that the absorption of diquat through intact skin is expected to be low. To be consistent with the USEPA approach for the residential exposure assessment, a dermal absorption factor of 4.1% was used by the PMRA for the assessment of occupational exposure for workers mixing/loading and applying diquat using handgun equipment.

3.3 Comment on the Use of a Respirator

Initially, the USEPA mitigated any potential risk of occupational exposure by requiring all mixers/loaders/applicators to wear a dust/mist filtering respirator (Mine Safety and Health Administration / National Institute of Occupational Safety and Health [MSHA/NIOSH] approval number prefix TC-21C). Syngenta submitted two chemical-specific biomonitoring exposure studies - one for backpack applications of diquat and the other for groundboom applicators of paraquat, which was deemed a suitable surrogate chemical. Based on the results of the revised risk assessment the USEPA determined that a respirator was no longer required. Protective requirements were amended by the USEPA to a face shield for mixers/loaders using groundboom and backpack equipment.

Response

The two exposure studies mentioned by the Registrant (for the mixer/loader/applicator using backpack and groundboom equipment) were submitted to the PMRA. In addition, the registrant submitted a published exposure study for the mixer/loader/applicator using handgun equipment. The exposure studies were found acceptable by the PMRA and were used in a revised risk assessment for commercial workers.

Using exposure data from these studies, the PMRA determined that the calculated inhalation margins of exposure (MOEs) for workers using groundboom equipment (MOE of 24), backpack sprayer (MOE of 24) or handgun equipment (MOE of 2) are below the target MOE of 100. Therefore, the removal of a respirator from the Canadian labels is not justified. Consequently the PMRA's requirements for personal protective equipment remain unchanged.

3.4 Comment on Restricted-Entry Interval

A quantitative re-entry exposure assessment was conducted by the USEPA and due to acceptable MOEs, the 24-hour restricted-entry interval (REI) was reinstated for agricultural uses. For non-Worker Protection Standard (non-WPS) uses, a statement of "when sprays are dry" was permitted rather than a 4-day REI. Syngenta requests that the PMRA considers adopting these same conclusions.

Response

The PMRA found the USEPA's re-entry exposure assessment acceptable and a 24-hour REI is recommended for agriculture uses in Canada. For all other terrestrial uses (other than aquatic) a standard 12-hour REI is recommended.

3.5 Comment on Application Rates

The application rates mentioned in the Proposed Re-evaluation Decision are inaccurate. The Canadian label guarantee (on the Reward and Reglone labels) of 240 g/L is for the diquat ions. It appears that the application rates in the Proposed Re-evaluation Decision were calculated as if this was the rate of diquat.

Response

In the Proposed Re-evaluation Decision for diquat, the application rates were expressed in units of cation (ci) and diquat products were considered to be formulated with 53.5% of the diquat cation. The PMRA recalculated all application rates according to the above comment. Based on the recalculated application rates, the human health and environment sections of the Proposed Re-evaluation Decision were revised for diquat. There were no significant changes to the re-evaluation decision as a result of this revision.

4.0 Comments on the Buffer Zones

In the Proposed Re-evaluation Decision published for diquat, the PMRA proposed buffer zones for aerial application for the protection of terrestrial habitat of 70 to 100 metres. The registrant considers this distance to be too large to permit practical use of the product given the size of fields typically used. Syngenta suggests that a 25-metre buffer zone would be adequately protective of off target vegetation at wind speeds of 2 to 16 km/hr with coarse to medium standard flat fan nozzles, and the worst case effects that might occur beyond 25 metres downwind would be temporary. This is based on:

The use of giant duckweed as the most sensitive species indicator shows that plant species are most sensitive; therefore, "use experience" from off-target terrestrial plants is relevant. Use experience shows that off target damage to adjacent vegetation beyond 20 metres downwind has not been of concern.

- Diquat acts only locally by contact with leaf tissue and this reduces the impact of doses that correspond to application rates below the minimum rate. Consequently, model predictions are considered overprotective.
- The model used by the PMRA to calculate buffer zones assumed worst case drift (100% of all application) whereas most applications are not done under worst case conditions.

Response

- Syngenta has recommended an aerial application buffer zone of 25 metres to adequately protect off-target vegetation for a 2 to 16 km/hr wind speed and a coarse to medium spray quality. Syngenta has indicated that this recommendation is based on their "use experience" with adjacent terrestrial plants and observance of temporary effects on non-target vegetation downwind from the point of application. Therefore, the PMRA, requests that these data be submitted to substantiate the assertion that buffer zones for diquat are overly protective for terrestrial habitats.
- The component of spray drift that settles out (known as the deposit fraction) will come into contact with leaf surfaces of non-target vegetation. The terrestrial plant toxicity data indicates that the threshold for effects is the effect concentration 25% (EC₂₅). The spray drift model predicts the downwind distance at which the deposit of diquat onto plant surfaces is equivalent to the EC₂₅. On this basis, model predictions are not considered as overly protective for non-target vegetation.
- 3) Buffer zone models (for example, AGricultural DISPersal [AgDISP]; PMRA ground application model) are not based on a "worst case" drift scenario which assumes 100% of the application rate as potential drift. Spray drift in itself is a fraction of the application rate and consists of a deposit fraction and an airborne or aloft fraction. Buffer zone predictions are based only on the spray deposit fraction of spray drift.

In consideration of the comments pertaining to buffer zones, the PMRA has concluded that the information provided does not affect the assessment of the prescribed buffer zones as outlined in the Proposed Re-evaluation Decision for diquat.

Appendix II Label Amendments for Products Containing Diquat

NOTE: The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of Commercial and Restricted class end-use products containing diquat in Canada must be amended to include the following statements to further protect workers and the environment.

 The following statements must be included in the PRECAUTIONS section of all commercial end-use products.

Wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves and footwear, goggles and a respirator during mixing/loading and application, chemical-resistant headgear for overhead applications and a chemical-resistant apron when cleaning equipment, mixing/loading.

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing immediately if pesticide comes in contact with skin through soaked clothing or spills. Then wash skin thoroughly and put on clean clothing.

Users should remove personal protective equipment immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

 For terrestrial uses of diquat, i.e. the end-use product Regione Desiccant, Registration Number 26396, the following statement must be included in the PRECAUTIONS section.

DO NOT enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours for all agricultural uses. For all other terrestrial uses, DO NOT enter or allow worker entry into treated areas during the restricted-entry interval of 12 hours.

III) The following statement must be included in the DIRECTIONS FOR USE section of all commercial end-use products.

Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and parks is minimal. Take into consideration meteorological conditions (e.g. wind speed, wind direction, temperature inversion) and application equipment and sprayer settings used for application.

IV) For terrestrial uses of diquat, including the end-use product Regione Desiccant, Registration Number 26396, the following statement must be included in the DIRECTIONS FOR USE section.

Mixers and loaders supporting aerial applications are required to use closed systems.

V) For end-use products containing diquat with uses both on agricultural and noncropland, including Reglone Desiccant, Registration Number 26396, the following statements must be included in the DIRECTIONS FOR USE section.

<u>Field sprayer application</u>: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

Aerial application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. Suggested conditions for good aerial application are **moderate temperatures** (less than 25°C) and **humidity** (greater than 50%). DO NOT apply when wind speed is greater than 9 km/h at flying height at the site of application. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. To minimize spray drift, use flat fan or hollow cone nozzles, and a pressure of 150–200 kPa, with the nozzles pointed back 150°–180°. REGLO-JETTM nozzles are available for aerial application. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length MUST NOT exceed 65% of the wingspan or rotorspan.

For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies which minimize off-site drift, including meteorological conditions (e.g. wind direction, low wind speed) and spray equipment (e.g. coarse droplet sizes, minimizing height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.

Buffer zones:

Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Стор		Buffer Zones (metres) Required for the Protection of:		
			Aquatic Habitat of Depths:		Terrestrial
			Less than 1 m	Greater than 1 m	Habitat
Field sprayer*	Beans, canola, flax, lentils, mustard, peas, sunflower, chickpeas, legume forage seed crops, oats, sweet white lupins		5	3	3
	Vegetable and field crops, fruit, non- cropland (including rights-of-way**), potatoes		10	5	5
Aerial	Beans, legume forage seed crops	Fixed wing	150	80	90
		Rotary wing	100	55	70
	Potato	Fixed wing	200	100	100
		Rotary wing	125	65	80

For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

** For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required. When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

VI) For end-use products containing diquat for use on terrestrial non-agricultural areas, including Reward Aquatic Herbicide, Registration Number 26271, the following statements must be included in the DIRECTIONS FOR USE section.

<u>Field sprayer application</u>: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

For terrestrial application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies which minimize off-site drift, including meteorological conditions (e.g. wind direction, low wind speed) and spray equipment (e.g. coarse droplet sizes, minimizing height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.

Buffer zones:

Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application		Buffer Zones (metres) Required for the Protection of:			
	Use Site	Aquatic Ha			
		Less than	Greater than	Terrestrial Habitat	
Field sprayer*	Non-cropland (including rights-c*-way**) and chemical mowing	10	5	5	

For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

VII) The following statements must be included in the ENVIRONMENTAL HAZARDS section of all commercial end-use products.

TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

- VIII) For products with aquatic uses, including Reward Aquatic Herbicide (Registration No. 26271), the label should be amended to reflect that repeat application of diquat to water bodies is prohibited for two weeks after application in order to protect aquatic organisms.
- IX) For the end-use product Reward Aquatic Herbicide (Registration Number 26271), the following statement must be removed:

Apply 2.3 to 4.5 litres in a minimum of 225 litres per hectare of water.

The statement must be replaced by the following:

Apply 2.3 to 4.5 litres in a minimum of 225 litres of water per hectare.

- Non-cropland should be identified as rights-of-way for transportation or utility corridors, airports, wasteland, garbage dumps and industrial parks.
- XI) The Registrant is required to clarify which vegetables receive "inter-row-weeding" treatment with diquat and define areas where diquat is used for chemical mowing.

